

REMARKS

Reconsideration of this Application and entry of these Amendments is respectfully requested. By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which they are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

No new matter has been added as a result of the present amendments.

In the claims

Claims 1-3, 5-16, 18-20, and 29 are pending in this application.

Claims 1, 9, and 16 have been amended to further clarify the claimed subject matter. Support for these amendments can be found throughout the claims as filed, for example in Table 3.

Double Patenting Rejection

The Office provisionally rejects claims 1-3, 6-16, 18-20, and 29 as being unpatentable over claims 19, 27, and 34 of co-pending Application No. 12/256,665. Respectfully, Applicants elect to postpone responding until the rejection is no longer a "provisional" rejection.

Applicants believe the election to postpone a response is appropriate in view of the MPEP at 804(I)B which states,

"The 'provisional' double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that 'provisional' double patenting rejection is the only rejection remaining in at least one of the applications."

35 U.S.C. §103 Rejections

The Office Action rejects claims 1-3, 10-16, 19-20, and 29 under 35 U.S.C. §103(a) as being unpatentable over Bigal *et al.* (Cephalalgia, 2002, 22, p. 432-438; "Bigal") in view of Cephalalgia, An International Journal of Headache,

Volume 24, Supplement 1, 2004 (“Cephalalgia”) in view of Loder *et al.* (The Clinical Journal of Pain, 18:S169-S176, 2002; “Loder”). Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, the Office must meet four conditions. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art itself would have *provided* one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant’s disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a suggestion, teaching, or motivation to combine the prior art references (“the TSM test”). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). *KSR Int’l Co. v. Teleflex, Inc.*, teaches that this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). Nevertheless, the TSM test captures the important insight that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

The Bigal reference reviews the International Headache Society (IHS) diagnostic criteria for chronic daily headaches and proposes revisions to those criteria (Abstract). Bigal does not teach or suggest the administration of botulinum toxin to treat headaches in triptan medication overuse patients.

The cited Cephalalgia 2004 reference presents prospective diagnostic criteria for medication-overuse headaches. The reference does not teach or suggest specific methods of treating such headaches and certainly does not

teach the administration of botulinum toxin to treat triptan medication overuse headaches.

The Office then turns to Loder which teaches the use of botulinum toxin to treat migraine headaches, chronic daily headaches (defined as more than 15 days per month), tension-type headaches, and post-whiplash headaches. (Abstract). Loder does not teach or suggest the use of botulinum toxin to treat triptan medication overuse headaches, wherein both the headache exacerbation caused by the triptan overuse and the actual use of triptan medication is treated by the botulinum toxin. In addition, the combination of these references fails to disclose or suggest the particularity and specificity of the instantly claimed method, namely the specific range of botulinum toxin administration in an amount between about 105 and about 260 units. Further, the Loder reference teaches away from the present claims. For example, the Loder reference describes a study wherein patient Group 1 received placebo, Group 2 received 25 units of botulinum toxin, and Group 3 received 75 units of botulinum toxin. At page S171, Loder states:

Compared with Group 1, the patients in Group 2 experienced significantly fewer migraine attacks per month, as well as reductions in peak migraine severity, number of days of acute headache medication use, and incidence of vomiting. In contrast, no significant differences observed between Groups 1 and 3 on any outcome measures.

Applicants note the pending claims specify injections of between about 105 and about 260 units, well above that amount described in Loder as no better than the placebo. Thus, rather than suggesting the method of the pending claims, Loder teaches away by describing the positive effects of 25-unit treatments while labeling the 75-unit treatments as ineffective. It is significant that the dosage specified by the pending claims is considerably higher than that described in Loder, as one of skill in the art would not find a positive result at 25 units combined with no results at 75 units to suggest treatments of greater than 105 units, especially in the case of neurotoxins capable of killing patients.

This passage in Loder also demonstrates the unexpected results achieved with the methods of the present invention, as one of ordinary skill in the art would read Loder to suggest lower doses of botulinum toxin were more effective, not the higher doses presently claimed.

Thus, Applicants respectfully ask that the rejection be withdrawn.

Conclusion

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and a Notice of Allowance to that effect is respectfully requested. The Commissioner is hereby authorized to charge any additional fees which may be required for entry of this paper, or credit any overpayment, to Deposit Account No. 01-0885. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, the Examiner is kindly urged to call the undersigned at telephone number (714) 246-6458.

Respectfully submitted,

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